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**Datasheet for the decision
of 19 August 2014**

Case Number: T 1014/11 - 3.2.02

Application Number: 00311669.6

Publication Number: 1110566

IPC: A61M1/38, A61M1/36, A61M1/30

Language of the proceedings: EN

Title of invention:
Extracorporeal blood processing apparatus

Patent Proprietor:
Terumo BCT, Inc.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(c), 54, 56, 111(1)
RPBA Art. 12(4), 13(1)

Keyword:
Added subject-matter (no)
Novelty (yes)
Inventive step (yes)

Decisions cited:
G 0010/91

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 1014/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 19 August 2014

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
4 March 2011 concerning maintenance of European
patent No. 1110566 in amended form.**

Composition of the Board:

Chairman E. Dufrasne
Members: M. Stern
C. Körber

Summary of Facts and Submissions

- I. Appeals were lodged by both the opponent and the patent proprietor against the interlocutory decision of the Opposition Division, posted 4 March 2011, concerning the maintenance of European patent No. 1 110 566 in amended form.
- II. The opponent filed a notice of appeal on 6 May 2011, paying the appeal fee the same day. A statement setting out the grounds of appeal was filed on 14 July 2011.
- III. The patent proprietor filed a notice of appeal on 12 May 2011, paying the appeal fee the same day. A statement setting out the grounds of appeal was filed on 5 July 2011.
- IV. In the following, the appellant-proprietor will be referred to as the "proprietor", and the appellant-opponent as the "opponent".
- V. The following documents are cited in the decision:
 - D1: US-A-5 795 317
 - D2: EP-A-0 834 329
 - D5: US-A-4 596 550
 - D6: US-A-3 946 731
 - D7: WO-A-92/02 264
 - D8: US-A-5 965 089
 - D9: US-A-5 941 842
 - D10: Gebrauchsanweisung Blutzellseparator AS 104, Fresenius, 4/6.90 (GA)
 - D12: DE-T2-36 87 453
 - D13: US-A-4 715 849
 - D15: DE-A-196 05 260
 - D16: WO-A-97/10 013.

VI. By letter dated 14 August 2014, the opponent filed document D16 and presented a new line of attack concerning inventive step, based on D7 in combination with D16.

VII. Oral proceedings were held on 19 August 2014.

The opponent requested that the decision under appeal be set aside and that the patent be revoked. At the oral proceedings, the opponent also requested for the first time that the proprietor's appeal be held inadmissible.

The proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of the first to fifth auxiliary requests filed with letter dated 5 December 2011.

The proprietor also requested the opponent's appeal be held inadmissible. It requested moreover that neither the fresh ground of opposition under Article 100(b) EPC nor the late-filed documents D12, D13, D15 and D16 be admitted. It also requested the Board not to admit those objections presented by the opponent in its statement of grounds of appeal which had not already been raised during the opposition period, or had not been considered or decided upon in the first-instance proceedings. If they were admitted, the Board was requested to remit the case to the Opposition Division.

VIII. Claim 1 of the main request (i.e. of the patent as granted) reads as follows:

"An extracorporeal blood processing apparatus (6) adapted to cooperate with an extracorporeal blood circuit (10), comprising:

a fluid pressure-monitoring device (1200, 1260) for sensing a pressure in the extracorporeal blood circuit (10);

at least one fluid flow control device (1020, 1030, 1040, 1060, 1090) for circulating at least one liquid in the extracorporeal blood circuit (10); and

a control device for receiving a pressure signal from the pressure monitoring device (1200, 1260) and comparing it to a threshold value, and for causing the operation of the at least one flow control device (1020, 1030, 1040, 1060, 1090),

characterized in that the control device is programmed for:

- stopping the at least one fluid flow control device (1020, 1030, 1040, 1060, 1090), when the fluid pressure sensed by the fluid pressure monitoring device (1200, 1260) is below the threshold value; and
- resuming the operation of the at least one flow control device (1020, 1030, 1040, 1060, 1090), when the fluid pressure sensed by the fluid pressure monitoring device (1200, 1260) rises above the threshold value within a selected period of time or a discrete set point within a selected period of time."

Claims 2 to 14 of the granted patent are dependent claims.

IX. The arguments of the appellant-opponent ("opponent") relevant for the present decision are summarised as follows:

- At the oral proceedings, it had requested that the proprietor's appeal be rejected as inadmissible. Since the inadmissibility of an appeal was a procedural objection, a party was free to raise it at any time during the proceedings.

- The ground under Article 100(b) EPC should be admitted by the Board. The Opposition Division did not properly exercise its discretion when it found that the ground was prima facie not relevant and consequently did not admit it.

- All objections presented with the statement of grounds of appeal, in particular those under Article 100(c) EPC, should be considered. Moreover, the objections based on documents D12, D13, D15 and D16 should be also considered, since they were of high relevance. Also the late-filed objections concerning inventive step based on the document combinations D6 with D8, D8 with D10 and D2 with D10 were highly relevant and should thus be considered.

- There was no basis in the original application for the following expressions in granted claim 1: "stopping the at least one flow control device", "within a selected period of time" and "sensing a pressure". Original claims 15, 16, 17 and 21 did not provide a basis for granted claim 1. Claims 15 and 16 on the one hand, and claim 21 on the other, defined different alternatives which could not be combined. Claim 1 covered the possibility of pausing fewer than all pumps, as described in original paragraph [0044], in

contradiction to original paragraph [0040] which indicated the pausing of all pumps. Moreover, the features of a "warning alarm signal" and a "full alarm condition" appearing in original paragraph [0040] and of a "fluid chamber 67" appearing in original paragraph [0044] were missing in granted claim 1.

- Documents D2, D5, D7, D8, D9 and D12 took away the novelty of the system of granted claim 1. In particular, the "selected period of time" in the claim had to be interpreted as a variable period defined by the time taken for the pressure to recover, and not as a set time limit programmed into the system.

- The system, moreover, lacked inventive step in view of each of the following documents or combinations: D5 alone, D6 with D7, D7 with D6, D2 alone, D15 with D7, D10 alone, D6 with D8, D8 with D10, D2 with D10 and D7 with D16. Paragraph [0006] of the granted patent explained that it was well known to activate an alarm for operator intervention and/or pump controls such as pump slowing or stoppage as a result of sensing unusual pressure values. There could therefore be no inventive merit in the present definition of stopping and resuming the fluid flow. In particular, even assuming that the closest prior art D7 did not disclose waiting a selected period of time until the pressure had recovered, this feature became obvious in view of the fact that D6 disclosed the resumption of flow after it had been stopped when pressure remained outside a certain range for a certain period.

X. The arguments of the appellant-proprietor ("proprietor") relevant for the present decision are summarised as follows:

- The opponent had failed to give any reason for waiting until the oral proceedings to file its request to reject the proprietor's appeal as inadmissible. The need for procedural economy mandated that the request should not be admitted at this late stage.

- With reference to G 10/91, no consent was given for considering the fresh ground of opposition under Article 100(b) EPC.

- The Board should not admit those objections which had not been presented in the opposition period since it would give the opponent a tactical advantage by filing documents or arguments at a late stage in the procedure. D12, D13 and D15 should not be admitted since they had been filed late during the first-instance proceedings and, moreover, the Opposition Division had correctly not admitted D12 and D13, and D15 was of little relevance. Also D16 should not be admitted since the opponent had presented no reason for filing this document only two working days before the oral proceedings although it was well known to the opponent who had recently carried out opposition-appeal proceedings against D16. Furthermore, there was no reason to allow the opponent to present for the first time at oral proceedings new lines of attack concerning inventive step (D6 with D8, D8 with D10 and D2 with D10). If any of the objections which the proprietor considered to be inadmissible were nevertheless admitted, the Board was requested to remit the case so that they could be considered by the Opposition Division.

Reasons for the Decision

1. Admissibility of the proprietor's appeal

The admissibility of the proprietor's appeal remained undisputed until the beginning of the oral proceedings. The opponent then argued that the inadmissibility of an appeal was a procedural objection which a party was free to raise at any time during the proceedings.

However, as correctly pointed out by the proprietor, the opponent failed to give any reason for waiting until oral proceedings to confront the proprietor and the Board for the first time with this request, which constitutes an amendment to the opponent's case as presented in its statement of grounds of appeal. The Board itself also fails to see any reason why the proprietor's appeal might not be admissible.

Thus, in the absence of any justification for the late filing of the request and in view of the need for procedural economy, the Board declines to admit the request, in the exercise of its discretion under Article 13(1) RPBA.

Consequently, the Board considers the proprietor's appeal to be admissible.

2. Admissibility of the ground of Article 100(b) EPC

In the notice of opposition, the contested patent had been opposed under Article 100(c) and 100(a) EPC, the latter regarding the requirements of novelty and inventive step. The ground for opposition of Article 100(b) EPC, however, had not been raised and substantiated in the notice of opposition and had not

been admitted by the Opposition Division since it found it to be *prima facie* not relevant. The fact that the Opposition Division arrived at this and not at the opposite conclusion is not sufficient reason to consider that the exercise of its discretion was faulty, as held by the opponent.

Therefore, the ground under Article 100(b) EPC is a fresh ground of opposition, which, following opinion G 10/91, could be considered in the present appeal proceedings only with the approval of the proprietor. Since the proprietor has not given that approval, the ground under Article 100(b) EPC is not to be considered.

3. *Article 100(c) EPC*

3.1 The Board finds it appropriate to consider all objections under Article 100(c) EPC brought forward by the opponent in its statement of grounds of appeal, in particular since they are very similar and related to those which have already been considered in the impugned decision (Article 12(4) RPBA). As it follows from Article 111(1) EPC that there is no right to have each and every objection considered by two instances, the Board sees no valid justification for remitting the present case to the first instance.

3.2 Independent claim 1 of the granted patent is primarily based on independent claim 15 of the application as originally filed. Claim 1 of the granted patent contains additional limitations which the Board considers to be directly and unambiguously derivable from the original application, in particular from claims 16, 17 and 21 and paragraphs [0040] and [0041], for the reasons detailed hereinafter:

3.2.1 *"stopping the **at least one** flow control device"*

Original independent claim 15 already contains the feature of "at least one flow control device", and then goes on to define "said flow control device to halt fluid flow". However, in the light of paragraph [0041], in particular line 44 mentioning fluid flow controls "stopping the flow or flows o(f) pump or pumps", it becomes clear that what is stopped according to original claim 15 is the "at least one flow control device". Accordingly, the claim wording does not require that the complete fluid flow is halted, as argued by the opponent.

Claim 1 of the granted patent covers the embodiments of stopping a single pump or stopping a plurality of pumps. As indicated above, paragraph [0041] explicitly mentions the plurality of pumps, and also paragraph [0040] explicitly mentions (in line 25) the pausing of "all pumps" (of, obviously, a plurality of pumps). The opponent contended that, in the light of paragraph [0044], claim 1 of the granted patent covered the possibility of pausing "less than all" pumps. The Board, however, does not consider this contention to be of relevance in the present context since, as indicated above, claim 1 implies the pausing of all pumps of a plurality of pumps.

3.2.2 *"resuming the operation of the at least one flow control device when the fluid pressure sensed by the fluid pressure monitoring device rises above the threshold value **within a selected period of time** or a discrete set point **within a selected period of time**"*

Original independent claim 15 states that the fluid flow is halted "for a selected period". Original dependent claims 16 and 17 define this selected period as the time it takes for the pressure to recover. Original claim 21 is attached to claims 16 and 17 and defines the selected period as a set time limit. Thus, according to claim 21, if the pressure does not recover in the "selected period" as defined by claim 16 or claim 17, the selected period is the "set time limit" defined by claim 21. This interpretation finds support in paragraph [0040], in particular in lines 29 to 31, where it is said that the set time limit is a *further* condition to that of the pressure being above the threshold.

3.2.3 "**sensing** a pressure"

In the overall context of the present application, the Board considers the expression "sensing" a pressure, which appears in claims 1 to 3 and paragraph [0039] of the application as filed, to be synonymous with the expression "measuring" a pressure as used in original independent claim 15.

3.2.4 "*warning alarm signal*", "*full alarm condition*" and "*fluid chamber 67*"

The opponent argued that the features of a "warning alarm signal" and a "full alarm condition" appearing in paragraph [0040] and of a "fluid chamber 67" appearing in paragraph [0044] were missing in claim 1 as granted.

However, the Board considers that the application as filed clearly shows that these features are merely optional or preferred features. This is evidenced for example by the fact that the "warning alarm signal" and

the "full alarm condition" are originally defined as an option in dependent claims (in original claims 18 and 22), and that paragraph [0044] refers to an "embodiment *particularly* involving a fluid chamber such as chamber 67" (emphasis added).

3.2.5 The Board therefore concludes that the subject-matter of claim 1 does not extend beyond the content of the application as filed.

4. *Article 100(a) EPC - admissibility of facts and evidence*

4.1 The proprietor requested the Board not to admit documents D12 and D13, which had been filed late during the first-instance proceedings (after the opposition period) and were not admitted by the Opposition Division, in particular since they *prima facie* lacked relevance. It also requested that late-filed document D15 not be admitted (irrespective of its admission by the Opposition Division) as it also lacked relevance.

The Board considers, however, that the Opposition Division correctly exercised its discretion not to admit D12 and D13 and to admit D15, based on a *prima facie* assessment of the respective relevance of these documents. Hence, according to established jurisprudence, the Board should not overrule this decision (Case Law of the Boards of Appeal, IV.E.3.6, 7th Edition 2013). The Board itself fails to recognise any particular relevance of documents D12 and D13 which might prompt it to introduce them *ex officio* under Article 114(2) EPC.

Consequently, documents D12 and D13 are not admitted into the appeal proceedings, whereas document D15 is (Article 12(4) RPBA).

- 4.2 The Board also follows the proprietor's request not to admit document D16 which had been introduced extremely late into the appeal proceedings, namely two working days before the oral proceedings, in support of a new line of attack concerning inventive step (starting from D7). The opponent gave no valid reason for the late filing of this new objection, which is an amendment to its case as presented in its statement of grounds of appeal.

Hence, in view of the need for procedural economy, the Board does not admit D16 into the proceedings, in the exercise of its discretion under Article 13(1) RPBA.

- 4.3 During oral proceedings, the opponent introduced for the first time further lines of attack concerning inventive step based on the combinations of D6 with D8, D8 with D10 and D2 with D10. The opponent explained that only in preparing for the oral proceedings had it realised the relevance of these new lines of attack.

The Board does not accept this argument as a sufficient justification for amending the opponent's case as late as during oral proceedings. Consequently, in view of the need of procedural economy, the Board does not admit these new lines of attack under Article 13(1) RPBA.

- 4.4 The proprietor also requested the Board to disregard those lines of attack (on novelty and inventive step) which were presented by the opponent in its statement of grounds of appeal but were not considered or decided

upon in the first-instance proceedings. If they were admitted, the Board was requested to remit the case to the Opposition Division.

In line with the rationale expressed above under point 3.1, the Board also finds the objections concerning novelty and inventive step raised by the opponent in its statement of grounds of appeal to be very similar to those which have already been considered in the first-instance proceedings. The Board finds it appropriate therefore to consider them all, in particular without remitting the case to the Opposition Division.

5. *Article 100(a) EPC - novelty*

5.1 As explained in paragraph [0006] of the granted patent referring to the prior art, improper blood flow conditions in the access or draw needle of a blood flow circuit manifest themselves in certain pressure conditions, which, when detected, may require operator intervention and/or pump controls such as pump slowing or stoppage. For example, document D1, cited in paragraph [0035] of the patent, discloses slowing down the blood inlet pump if the negative pressure sensed is less than a predetermined negative limit value. Once the pressure comes back into an acceptable range, the blood inlet pump is returned to its normal speed.

5.2 The device claimed in claim 1 of the granted patent relates in essence to an extracorporeal blood circuit in which, when the fluid pressure is sensed to fall below a threshold value, the fluid flow is stopped and then resumed only when the fluid pressure rises above the threshold value, or above a discrete set point, within a selected period of time.

It is to be particularly noted that claim 1 defines the control device to be programmed to resume flow if the pressure recovers **within a selected period of time**. The "selected period of time" is to be interpreted therefore as a set time limit that has been programmed into the system, and not just as a variable period of time defined only by the time it takes for the pressure to recover.

As described in paragraph [0040], the selected period of time can be set at about six seconds, to give the system a chance to correct itself automatically once a potential problem with the access site is detected. The pump is restarted only if the pressure recovers within this period of time. If it does not, a full alarm condition may be activated allowing the operator to investigate the access site and to restart pumping.

5.3 The opponent argued that documents D2, D5, D7, D8 and D9 were novelty-destroying. Moreover, at oral proceedings it asserted that D12 too was novelty-destroying. However, for the reasons given under point 4.1 above, D12 was not admitted into the proceedings.

As correctly pointed out by the proprietor, none of the cited (admitted) documents discloses the feature of a control device programmed to resume flow if the pressure recovers within a selected period of time.

5.3.1 Document D7 discloses (page 21, lines 7 to 15) the slowing or stopping of the pump when the blood pressure falls below an initial threshold value, and a complete stoppage and full alarm when the blood pressure falls below a lower alarm limit value (79 in Figures 9 and

10). In the paragraph bridging pages 31 and 32, it is disclosed that the system stops flow when an occlusion is detected and resumes the flow with a different regime reducing the maximum flow rate value. No disclosure is given for waiting a selected period of time within which the pressure recovers. There is moreover no such waiting time disclosed in connection with the prior-art knowledge presented in D7 on page 2, lines 4 to 13 and page 17, lines 21 to 27, according to which pumping is terminated until normal vein pressure is restored. Nor can the operation on discrete computer cycles of, e.g., 50 msec mentioned at page 10, lines 15 to 16 be regarded as implying such a waiting time.

5.3.2 Document D5 describes two prior-art alternatives. In the first one, described on column 2, lines 6 to 11, a venous pump is stopped when the fluid pressure is below a threshold value, and the fluid flow is resumed when the pressure is above another threshold value. There is however, no disclosure that the flow is resumed if the pressure recovers within a selected period of time. In particular, there is no such disclosure on column 2, lines 3 to 6, as argued by the opponent. In a second alternative prior-art embodiment (column 2, lines 31 to 41), two operating flow phases are alternated purely as a function of time, without any reliance on pressure measurements.

5.3.3 Documents D8 and D9 disclose slowing down the pump when the blood pressure falls below a threshold value. Reference is made in particular to column 15, lines 30 to 43 of D8; column 27, lines 36 to 54 of D9 (it may be noted that D9 is entirely equivalent to D1 mentioned under point 5.1 above, which was cited in paragraph [0035] of both the patent and the original application). Contrary to the opponent's view, slowing

down a pump is no disclosure of stopping the pump. This applies in particular to the successive slowing down steps 344 and 345 in Figure 14B of D8.

Hence, D8 and D9 fail to disclose not only the recovery of pressure within a selected period of time, but also the feature of previously stopping the flow, as required by claim 1.

5.3.4 Document D2 discloses an embodiment (page 5, lines 29 to 34 and page 4, lines 26 to 28) in which the blood pump is slowed down when the blood pressure falls below a threshold value. In another embodiment, D2 discloses (claim 7 and page 8, lines 26 to 30) the stopping of a replacement fluid pump when the fluid pressure falls below a threshold value. The fluid flow is then resumed after the pressure has recovered. In this last embodiment it is however not disclosed that the fluid flow resumes if the pressure recovers within a selected period of time.

5.4 In view of the fact that at least the feature of resuming the flow if the pressure recovers within a selected period of time is absent from each of the mentioned documents, the subject-matter of claim 1 is novel within the meaning of Article 54 EPC.

6. *Article 100(a) EPC - inventive step*

6.1 The opponent argued that the subject-matter of granted claim 1 lacked inventive step in view of each of the following documents or document combinations (disregarding those lines of attack which were not admitted into the proceedings as indicated under point 4.3 above): D5 alone, D6 with D7, D7 with D6, D2 alone, D15 with D7 and D10 alone.

6.2 Like documents D2, D5 and D7 mentioned above, documents D6, D15 and D10 also fail to disclose the resumption of flow when the pressure recovers within a selected period of time.

In particular:

6.2.1 Document D6 discloses slowing or even stopping the pumping when the pressure remains outside a certain range for a certain period (column 2, lines 38 to 42 and 54 to 58; column 14, lines 41 to 48). Once the system has stopped or "shut down" as indicated in column 14, lines 45 to 48, it is clear that it will resume operation only under the control of an operator. That is, after stopping, the system itself does not resume operation when the pressure is restored within a selected period of time.

6.2.2 Document D15 discloses that when the pressure falls below a certain value, pumping is slowed down or even stopped, and then resumed when the pressure increases again (page 24, lines 34 to 36). There is no disclosure of setting a selected period of time for the flow resumption.

6.2.3 In document D10, the second line of the table of page "7-13" does not directly disclose that flow is stopped when the pressure is below a certain value. Moreover, page "3-12" does not disclose that flow is resumed when the pressure is above a certain value within a selected period of time.

6.3 Thus, from whichever of the aforementioned documents the skilled person departs, in the absence in all cited documents of any disclosure or suggestion of a control

device programmed to resume the flow when the pressure recovers within a selected period of time, the skilled person would not be led in an obvious way to the claimed subject-matter.

Stopping the flow gives the system the possibility of recovering from a pressure problem, after waiting a selected period of time to do so. After this time (if there has been no pressure recovery), the system may set a full alarm to allow intervention by the operator (page 7, lines 23 to 26). In this way the operator is called only when there is a serious (long-lived) pressure constraint that needs operator attention. By allowing the system to automatically restart itself within a "selected period of time", the operator is called upon less often to restart the system, as compared to D6 or D7, for example, where an alarm is sounded upon detection of a fault condition (i.e. when outside the "acceptable range" of D6 or when below the "lower alarm limit" of D7). This provides a clear technical contribution in view of the cited prior art.

6.4 The Board therefore comes to the conclusion that the subject-matter of claim 1 of the granted patent satisfies the requirement of inventive step within the meaning of Article 56 EPC. This finding applies, a fortiori, to the preferred embodiments defined in dependent patent claims 2 to 14.

7. There is consequently no need for the Board to establish the admissibility of the opponent's appeal and to examine the auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated